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WYETH,

Petitioner,

v.

DIANA LEVINE

Respondent.

On Writ of Certiorari to the Supreme Court of Vermont

BRIEF OF THE NATIONAL CONFERENCE OF STATE LEGISLATURES AS *AMICUS CURIAE* SUPPORTING RESPONDENTS

ELIZABETH J. CABRASER*
SCOTT P. NEALEY
LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP
275 BATTERY STREET, 30TH FLOOR
SAN FRANCISCO, CA 94111-3339
TELEPHONE: (415) 956-1000
FACSIMILE: (415) 956-1008

* *COUNSEL OF RECORD FOR THE AMICUS CURIAE*

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INTEREST OF THE *AMICUS CURIAE*

Amicus, the National Conference of State Legislatures, represents State Legislatures throughout the United States.[1] State governments, and their legislatures, as independent branches of co-equal States in our system of Federalism, are deeply involved in the creation of State tort laws. As such, State Legislatures have been on the front line of the policy decisions about "Tort Reform." In some cases, this involvement has included drafting, holding extensive hearing on, and either passing bills which enact similar preemption rules to that recently advocated by the Federal Executive Branch in its "Preamble;" or, in other instances, rejecting such rules of preemption. At least 40 States have enacted comprehensive statutes to govern products liability claims and recoveries by their citizens. Given the substantial and sustained exercise of State authority in the area of State tort law since the enactment of the Constitution, *Amicus* has a substantial interest in opposing policy statements – like that recently made by the executive branch through the FDA's preamble – that attempt to seize, without the involvement of Congress and the normal legislative process, and through circumvention of Executive Or-

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[1] The parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to its preparation or submission.

der 13132 "Federalism" (8/4/1999), entire areas of State authority.

Moreover, the question of whether a federal agency can, without a grant of authority to preempt from Congress, dictate preemption as a matter of agency policy has significant fiscal implications for State governments. Consumers' injuries do not simply vanish, nor are they magically healed, when the claims are preempted. Instead, the costs of their injuries are paid by insurers, borne by the individuals themselves, and, if the injured consumers cannot pay and are uninsured, State governments may pay (in whole, or with matching federal funds) for medical expenses and disability payments. These and other social costs, and the countervailing impact on States' economies of consumer litigation, have been the focus of much debate and legislation in the States. This vital decision-making process is a key part of our cooperative system of Federalism, and one which *Amicus* has a direct interest in preserving.

STATEMENT OF THE CASE

A. Federalism and Executive Order 13132

Executive Order 13132, aptly titled "Federalism" (Aug. 4, 1999), recognized that "the States possess unique authorities, qualities, and abilities to meet the needs of the people and should function as laboratories of democracy." *Id.*, at § 2(c).[2]

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[2] Executive Order 13132 incorporates and expands on Executive Order 12612 (October 26, 1987), 52 Fed. Reg. 41685,

The Executive Order states that "[n]ational action limiting the policymaking discretion of the States shall be taken only where there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance." *Id.*, at § 3(b).

Section Four of the Executive Order outlines several "Special Requirements for Preemption." This section requires, *inter alia*, that federal agencies restrict to the minimum level necessary any regulatory preemption of State law (§ 4(c)); that federal agencies shall consult *prior to* publication of an NPRM with appropriate State and local officials in an effort to avoid the possibility of conflict between State law and federal interests (§ 4(d)); and that "when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings" (§4(e)).

The Executive Order further requires that "no agency shall promulgate any regulation that has federalism implications and that preempts State law, unless the agency, prior to the formal promulgation of the regulation . . . consulted with State and local

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3 C.F.R. (1987) Corp., p. 252, which remained in effect from 1987 till it was updated in 1999 with Executive Order 13132. Both orders required similar pre-notice of proposed rulemaking, consultation, and notification, and respect for State policy decisions.

officials early in the process of developing the proposed regulation;" (§ 6(c)(1)).

The mandatory language of this Executive Order applies to federal agencies under 44 U.S.C. § 3502(1) that are not considered to be independent regulatory agencies, as defined in 44 U.S.C. § 3502(5). Section Nine states that "[i]ndependent regulatory agencies are encouraged to comply with the provisions of this order." The FDA is not identified by name in either 44 U.S.C. § 3502(1) or 44 U.S.C. § 3502(5), but is not deemed to be an independent regulatory agency because it is a subdivision of the Department of Health and Human Services. The mandatory language of the Executive Order thus applies to the FDA.

B. The FDA's prior position and 2000 statement that preemption was not implicated by the new labeling rule.

When Congress enacted the Food, Drug, and Cosmetic Act ("FDCA") in 1938, it specifically rejected a proposal to include a federal private right of action for damages because Congress recognized that such actions already existed under state common law. *See generally, In re Paxil Lit.*, No. CV 01-07937, 2002 WL 31375497 at *1 (C.D. CA 2002) (Pfaelzer, J.) (discussing and citing legislative history); Adler & Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 924 & n.130 (1995). In 1962, when Congress passed amendments to the FDCA, it added a provision specifically stating that "[n]othing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law

which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law." Pub. L. No. 87-781, 76 Stat. 780, 793 (1962). Accordingly, consistent with the legislative mandate, for nearly 40 years the FDA has, prior to the current Administration, consistently taken the position that its labeling requirements represent *minimum standards* which do not preempt state law.[3]

In 1977, when the FDA revised the patient package insert for oral contraceptives, it stated that "whether particular labeling may alter a manufacturer's liability in a given instance cannot be considered as a dispositive factor by the Commissioner." 42 Fed. Reg. 37636, 37637 (1977). Two years later, the FDA declared that "[i]t is not the intent of the FDA to influence the civil tort liability of the manufacturer." 44 Fed. Reg. 37434, 37447 (1979). The agency has historically and consistently recognized, in harmony with the Executive Order, that product liability litigation asserting State law claims serves

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[3] Rather than discuss in detail the regulatory scheme, *Amicus* directs the Court to an Article by Former FDA Commissioner David A. Kessler, who was appointed by President George H.W. Bush, and reappointed by President William J. Clinton., which discusses in detail the FDA's prior positions and internal competence as these relate to drug labeling. *See* Kessler, D.A. and Vladeck, D.C., *A Critical Examination of the FDA's Efforts to Preempt Failure-To-Warn Claims*, 96 Geo. L.J. 461 (2008)

an important role in protecting the public. *See, e.g.*, 44 Fed. Reg. at 37447 (*citing McEwen v. Ortho Pharms. Corp.*, 528 P.2d 522 (Ore. 1974)). In doing so, the FDA acknowledged that compliance with agency labeling requirements does not supplant state tort doctrines, such as the manufacturer's continuing duty to warn of risks as they are discovered, noting that "drug labeling does not always contain the most current information and opinion available to physicians about a drug because advances in medical knowledge inevitably precede formal submission of proposed new labeling by the manufacturer and approval by FDA." *Id.* at 37435. Thus, "[c]ommunication of significant medical information should be encouraged, not restricted," and "the addition to labeling and advertising of additional warnings ... is not prohibited by [FDA's] regulations." *Id.*

In 1998, while issuing regulations addressing pharmacists' provision of written patient information ("Medication Guides") for certain types of prescription drugs, the FDA stated once again that its regulations established only *minimum standards* which posed no actual or anticipated conflict with state law, and which are not intended to preclude the imposition of additional labeling requirements. 63 Fed. Reg. 66378, 66384 (1998). Even though Medication Guides are subject to intense regulatory oversight by the FDA, *see* 63 Fed. Reg. 66378, the FDA reaffirmed its anti-preemption stance, and rejected comments from the pharmaceutical industry calling for the preemption of state labeling requirements, stating that "FDA regulations establish the minimal standards necessary, but were not intended to preclude states

from imposing additional labeling requirements. States may authorize additional labeling but they cannot reduce, alter, or eliminate FDA-required labeling." 63 Fed. Reg. at 66384.

The FDA took the same position in 2000 when it published its proposed drug labeling rule – the same rule now before this Court – declaring as follows:

> FDA has analyzed this proposed rule in accordance with Executive Order 13132: Federalism. The Order requires Federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt State law....
>
> FDA is publishing this proposed rule to revise its regulations governing the format and content of labeling for human prescription drug products.... ***[T]his proposed rule does not preempt State law.***
>
> ***Accordingly, FDA has determined that this proposed rule does not contain policies that have federalism implications or that preempt State law.***

65 Fed. Reg. 81082, 81103 (2000) (emphasis added).

Having expressly stated that the proposed new labeling rules did not have federalism implications or preempt State law, the FDA did not seek or receive

comments on the Federalism implication of preemption.[4]

C. The FDA's Change in Position

In 2001 a new Chief Counsel of the FDA, Daniel Troy, was appointed. Mr. Troy had represented pharmaceutical and other industries in lawsuits against the FDA. *See generally,* Schultz, S., *Mr. Outside Moves Inside: Daniel Troy fought the FDA for years; now he's helping to run it. U.S. News and World Report* (Aug. 7, 2008) (http://health.usnews.com/usnews/health/articles/030324/24fda.htm). Once Appointed, Mr. Troy publicly called for industry representatives to suggest cases in which the FDA could advocate for preemption. *See generally*, O'Reilly, J.T., *U.S. Food and Drug Regulation in Its First Century and Beyond*, 93 Cornell L. Rev. 939, 953-4 (July 2008). The FDA Subsequently began filing amicus briefs whose arguments mirrored the opinions expressed in the FDA's current preamble. No such position had ever been advocated in the over 90-year history of the FDA.[5] However,

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[4] In its Amicus Brief the United States has ignored this history, instead simply repeating the incorrect statement of the preamble itself that it was purportedly the "long standing view" of the FDA that its labeling regulations preempted state law as they were both a floor and a ceiling, while asserting that the preceding 65+ year record of FDA reaffirmation of nonpreemption are mere "snippets."

[5] While the FDA claimed it had filed four amicus briefs supporting preemption, none supported any type of field pre-

courts rejected the agency's argument. E.g., *In re Paxil Litigation*, 2002 WL 31375497 (C.D. Cal. Oct. 18, 2002); *Witczak v. Pfizer*, 377 F. Supp. 2d 726 (D. Minn. 2005); *Cartwright v. Pfizer*, 369 F. Supp. 2d 876 (E.D. Tex. 2005); *McNellis v. Pfizer, Inc.*, 2005 WL 3752269 (D. N.J. Dec. 29, 2005); *Zikis v. Pfizer, Inc.*, 2005 WL 3019409 (N.D. Ill. Nov. 8, 2005). *Peters v. AstraZeneca, L.P.*, 417 F. Supp. 2d 1051, 1056-57 (W.D. Wis. 2006); *Madden v. Wyeth, Inc.*, No. 3-03-CV-0167-BD, 2005 U.S. Dist. Lexis 19989, at *10 n.6 (N.D. Tex. Sept. 14, 2005); *Albertson v. Wyeth, Inc.*, 2003 Pa. Dist. & Cnty. Dec. Lexis 135, at *18-25 (Pa. C.P. July 8, 2003); *Caraker v. Sandoz Pharms. Corp.*, 172 F. Supp. 2d 1018 (S.D. Ill. 2001).

At the end of the day on December 30, 2005, the Executive Branch Liaison for *Amicus*, Susan Frederick, received a call from FDA intergovernmental staff. *Affidavit of Susan Parnas Frederick*, at 1 (attached hereto). The staffer told Ms. Frederick that the FDA planned to finalize its long-dormant labeling rule in early January 2006 and would be includ-

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emption based upon regulation. *See* Zieve, A.M., and Wolfman, B., *The FDA's Argument for Eradicating State Tort Law*, Toxics Law Reporter (BNA) Vol. 21, No. 21 (5/25/06) available at http://www.citizen.org/documents/PDFARTIC.pdf). Moreover, the FDA's brief to this Court in *Buckman v. Plaintiffs' Legal Comm.*, 2000 WL 1364441, at *17 (filed Sept. 13, 2000), cited by the FDA directly acknowledged, contrary to the FDA's current position, "the historic primacy of state regulation of matters of health and safety" and the appropriateness of a presumption against preemption of state-law claims *including* failure to warn claims. *Id.*

ing a statement preempting state laws. Ms. Frederick immediately asked, on behalf of the NCSL, to be placed in touch with FDA's general counsel's office, for a copy of the proposed "policy statement," for the consultation process under Executive Order 13132 to occur, and for the Notice and comment period to be re-opened. *Id.*

Ms. Frederick then received a call from the FDA's general counsel's office, and, as she states in her Affidavit:

> I was informed by Mr. Randy Luttig that NCSL could not review this proposed language in advance of its publication, that this telephone call constituted the consultation under Executive Order 13132, and that the comment period was closed and would not be reopened to permit NCSL to submit comments on the new language.
>
> In a follow-up conversation with FDA staff, I was informed that the FDA considers the requirement of Executive Order 13132 satisfied, and was again told I would not be able to review a copy of the proposed "policy statement." I subsequently learned that FDA had received and accepted numerous late, non-public, comments from industry on the proposed regulation.

Id. at 1-2.

Thereafter, with no further rule making or public notice, the FDA simply attached a "preamble" to its January 24, 2006 Final Rule on labeling which had

not, prior to its publication, seen the light of day. The FDA, attempting to explain away its failure to follow the requirements of Executive Order 13132, *see* 71 Fed. Reg. 3922, § 10, explained as follows:

> FDA sought input from all stakeholders on new requirements for the content and format of prescription drug labeling through publication of the proposed rule in the Federal Register. ***Although the proposed rule did not propose to preempt state law, it did solicit comment on product liability issues.*** FDA received no comments on the proposed rule from State and local governmental entities.

Id. (emphasis added). Those from whom the FDA supposedly "did solicit comment" were not further described or identified. With this as its only justification, the FDA stated that it "believes that it has complied with all of the applicable requirements under Executive Order 13132 and has determined that this final rule is consistent with the Executive Order." *Id.*[6]

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[6] In its submission to this Court, the United States claims the FDA's preamble is entitled to "substantial deference" yet fails to further explain or justify the FDA's failure to follow Executive Order 13132, or its inappropriate treatment of state and local interests under the Executive Order, the very behavior that divests the preamble of any entitlement to due deference.

Shortly after the FDA published its preamble, ranking members of both chambers of Congress wrote to the FDA strongly objecting to the agency's preamble comments. *See* Letter to Michael O. Leavitt from Edward M. Kennedy and Christopher J. Dodd (February 23, 2006) and Letter to Michael O. Leavitt from Henry A. Waxman, John D. Dingell, and Sherrod Brown (February 23, 2006) (http://dodd.senate.gov/index.php?q=node/3381). The legislators sharply criticized the FDA for attempting to "reverse[] a long-standing FDA policy of permitting complementary State activities intended to protect consumers from unsafe drugs." They also noted the fact that "neither affected state and local entities, nor the general public were given an opportunity to comment" because the FDA "provided no opportunity for dissenting views to be heard." (*Id.*) Finally, the legislators attacked the very foundation of the FDA's analysis, which abrogates the roles and powers of the legislative and judicial branches, accusing the FDA of relying on "misleading characterizations of the governing statute and irrelevant cases, while ignoring contrary legislative history." (*Id.*)

Amicus voiced similar objections, stating in a formal letter to the Secretary of Health and Human Services that the FDA's 180 degree shift in position, combined with its refusal to go through the legally required notice and comment process, constituted "an abuse of agency process and a complete disregard for our dual system of government.... It is unacceptable that FDA would not permit the states to be heard on language that has a direct impact on state civil justice systems nationwide." Letter to Mike Leavitt

from Steven J. Rauschenberger Assistant Senate Minority Leader, Illinois President, NCSL (January 13, 2006) (http://www.ncsl.org/programs/press/2006/060113leavitt.htm).

The FDA has come under increasing fire, from the medical profession itself (a constituency with undoubted relevant expertise), for its inability, through lack of funding and otherwise, effectively to regulate the products of pharmaceutical laboratories and safeguard the public health. Whether or not such criticism is invariably warranted, the FDA is unquestionably without the legal authority or expertise to regulate, much less nullify, the legislative and judicial products of the States' laboratories of democracy.[7] Announcements of preemption made without expertise, authority, or due process merit no deference.

As noted by Former Commissioner Kessler, subsequent to the FDA's issuance of the preamble, Congress passed and the President signed the FDA Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007) *which did not include a preemption*

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[7] As the New England Journal's editors have now expressly stated, the FDA's current preemptive position is also a threat to the medical profession. *See, e.g.*, Gurfman, G.D., Morrissey, S., Drazen, J.M., *Why Doctors Should Worry About Preemption*, NEJM, Vol. 359:1-3 (July 3, 2008) (editorial by NEJM editors, criticizing FDA position in this case) (available at http://content.nejm.org/cgi/content/full/359/1/1).

provision. The Act instead included a "rule of construction" that the FDA's new authority over labeling did *not* relieve manufacturers of their current responsibilities to provide up-to date safety information and did not affect their ability and responsibility to do so without first securing the FDA's approval; 121 Stat. 925-26; *see* Kessler and Vladeck at 469. As Commissioner Kessler notes, the pharmaceutical industry unsuccessfully sought a preemption provision; when they failed to secure one, opponents of the bill criticized it as "a definite boon to trial lawyers." *Id.* at fn 27. Whether it was a "definite boon" to consumers, their lawyers, pharmaceutical companies, or the State legislatures and courts that have long considered and balanced the interests of these constituencies in the system of tort law, the FDA Amendments Act definitely did *not* authorize preemption.

SUMMARY OF ARGUMENT

The FDA cannot deny that the preamble is not part of the FDA regulation and that it did not go though the formal notice and comment process. Although this Court has sometimes given deference to an agency's interpretive rules—rules that do not have the force of law, but that set forth the agency's understanding of a law which Congress has authorized that agency to interpret via the regulatory process or enforce, *e.g.*, *Auer v. Robbins*, 519 U.S. 452, 461 (1997)—in this case the FDA did not purport to issue an interpretive rule as Congress had not authorized the FDA to preempt or replace state tort law. Instead, the FDA stated its belief on a legal (or political) question, in language resembling a lawyer's

(or lobbyist's) advocacy position. *See* 71 Fed. Reg. 3922, 3934 and 3969 (2006).

However, even if this Court were to view the preamble as an interpretive rule, no deference can be given hereto without fundamentally undermining our system of Federalism for three reasons:

First, the FDA failed to give State authorities any meaningful notice and/or an opportunity to comment and participate in the proceedings as required by Executive Order 13132. The preamble's method of creation instead sought to preempt due process. The FDA's flagrant violation of a **binding** Executive Order designed to safeguard our system of Federalism should not be enabled by this Court.

Second, this procedural violation is exacerbated by the FDA's lack of Congressional authority to determine the preemptive effect of drug labeling rules on state law causes of action. The FDA has simply attempted to seize, in a manner never countenanced by this Court, the States' sovereign authority over their own tort law, in order to assist a special interest. Respect for our system of Federalism requires that this Court reject the Executive branch's effort to impose preemption absent clear Congressional authorization and appropriate respect for procedural norms.

Finally, when an Agency has radically changed its long-standing views, is unable to explain its change in view, and, as here, proceeds in a manner that demonstrates that politics, rather than independent Agency expertise, is the source of the new view, the Agency's arguments for administrative

preemption should be rejected out of respect for our shared system of Federalism. Preemption cannot be allowed to be *implied* based upon political decisions by the Executive Branch acting alone.

ARGUMENT

A. The FDA's Failure to Give The States Proper Notice and an Opportunity to Comment deprives the preamble of any force or entitlement to deference.

The FDA failed to comply with the express, unambiguous, and mandatory directive of Executive Order 13132. No sensible or reasoned excuse is provided by the FDA for its failure to consult with appropriate State officials. The FDA's tautological explanation that it need not consult them, having told States and Local Government in 2000 that the proposed regulations did not preempt state law, because it received no comments from them on Preemption, would make Charles Dodgson blush.[8].

Section 4(d) of Executive Order 13132 *requires* agencies to consult with appropriate State and Local officials whenever an agency foresees the possibility

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[8] Mr. Dodgson, writing as Lewis Carroll, presciently encapsulated the FDA's evident concept of due process in the innovation of his benevolent yet thrifty White Queen, who gave her maid "jam tomorrow and jam yesterday – but never jam today." Lewis Carroll, *The Annotated Alice* 247 (New American Library 1960), as cited in *Aka v. Wash. Hosp. Ctr.*, 156 F.3d 1284, 1301 (D.C. Cir. 1998).

of a conflict between state law and a federally protected interest within the agency's area of regulatory responsibility. Section 4(e) of Executive Order 13132 further specifies that when an agency proposes to act through adjudication or rulemaking to preempt state law, the agency *shall provide* all affected state and local officials with notice and an opportunity to comment and participate in the proceedings.

State Governments have a reasonable basis to rely upon the Executive Order and expect that the Federal Executive Branch would not engage in an end run around due process to avoid what it knew to be unfavorable input and opposition. *See Watters v. Wachovia Bank, N.A.*, – U.S. –, 127 S. Ct. 1559, 1584 (2007) (Stevens, J., Roberts, C.J., and Scalia *dissenting*). When the FDA issued its proposed drug labeling rule in 2000, it stated quite clearly in its notice of rulemaking that "***this proposed rule does not preempt state law.***" 65 Fed. Reg. 81103 (emphasis added). This unequivocal statement was consistent with the FDA's longstanding position on preemption. The FDA therefore expressly told State and local officials that the proposed rule would not preempt or otherwise impact state law, effectively silencing interested parties during the notice and comment period by assuring them that Federalism issues were not at stake.

The process by which the preamble was inserted inappropriately placed expediency above the necessary respect for State governments. *Cf. Community Communications Co., Inc. v. City of Boulder, Colo.*, 455 U.S. 40, 61 (1982) (Rehnquist, J., Burger, C.J.,

and O'Connor, J. dissenting) ("pre-emption, because it involves the supremacy clause, implicates our basic notions of federalism."). In its zeal to assist the peculiar interest of a pressure group, the agency knocked askew the balance of powers and the system of checks and balances—among the branches of our federal government, and between the federal and state governments—that are the structural and functional bedrocks of our system. *Gregory v. Ashcroft*, 501 U.S. 452, 548-9 (1991). Unbalanced and unchecked, the preamble exalts the bureaucratic processes of the executive branch and subordinates the legislative and judicial branches of both the Federal government, and the States themselves, without any Constitutional basis.

Moreover, the preamble ignores the historical roles of the States as sovereigns of their own statutory and common law, in an area in which Congress, deferring to the States, has not legislated: providing compensation for victims of negligence and strict liability in the design and manufacture of pharmaceutical products. Deferring to the preamble's administrative fiat would eradicate, in the guise of preemption, the compensatory and deterrent system, painstakingly built up over more than two centuries of State legislation and jurisprudence, in favor of a void. Preemption in this case is an undefined, unlimited, and an ill-fitting concept, since neither the FDA nor any other federal agency has ever entered, much less fully occupied, the compensatory tort system other than through formal statutory acts of Congress addressing specific medical products, such as with-vaccines, which provide comprehensive systems for

the adjudication of claims and redress of injuries. The preamble does neither. It is nihilism, not preemption.

While the Executive Branch is entitled to assert any position it wishes, it cannot both do so via a legal process which fails to afford State Governments the respect they are due under Federalism, and expect any deference to its views. *See Watters v. Wachovia Bank, N.A.*, 127 S. Ct. 1559, 1582 (2007) (Stevens, J., joined by the Chief Justice and Scalia, J., dissenting). There was certainly no emergency at issue here to justify the hidden process used to create the preamble. As noted above, the FDA's new views on preemption as expressed in amicus briefs had been repeatedly rejected by courts with sufficient time for the FDA to notify State Governments of its intended change in position (so as to comply with Section 4(d) of Executive Order 13132) if it so wished. Failure to do so is an implicit admission of the lack of merit in the FDA's changed position, and self evident unwillingness to have this position exposed to comment and objection by State Governments. This procedural failure is fatal to any application of the preemption language. *Cf. United States v. Mead Corp.*, 533 U.S. 218, 228 (2001)("power to persuade" is related to "thoroughness evident" in agency's consideration of the issue). To rule otherwise would deprive State and Local governments of important historical rights without giving them any voice in the proceedings, while rewarding what was essentially a bait-and-switch by the FDA. The FDA's new views, expressed in the preamble, are therefore entitled to no deference.

B. The FDA Acted Well Outside the Scope of the Authority Delegated to it by Congress and its New Presentation Position is *Ultra Vires*.

In *Riegel v. Medtronic, Inc.*, – U.S. –, 128 S. Ct. 999 (2008) this Court considered the FDA's interpretation of a phrase: "state or local requirements of generally applicability . . .," found in an FDA regulation. *Id.* at 1010. While noting that "substantial deference" could be afforded under *Auer v. Robbins*, 519 U.S. 452, 461 (1997) to the Agency's interpretation of terms in its own regulation, this Court stated that: "[w]e find the agency's explanation less than compelling," and untimely afforded no deference to the FDA's interpretation. *Riegel, id.* at 1011.

While acknowledging this Court's ruling in *Riegel*, the United States argues for *Auer* deference in this case. *United States* Amicus at 26. Yet, the United States failed to acknowledge or discuss the substantial differences between the FDA's action in this case and *Auer* and *Riegel*. These differences are critical in placing the appropriate limits on preemption to protect our system of federalism.

Auer involved regulations promulgated by the Secretary of Labor and published in the CFR establishing a "salary basis" test for overtime to implement the Fair Labor Standards Act. 519 U.S. at 455. These regulations were drafted under what this Court noted was a statutory grant to the Secretary of Labor of "broad authority to 'defin[e] and delimit' the scope of the exemption [in the FLSA] for executive,

administrative, and professional employees." *Id.* at 456.

Because a (1) regulation, (2) was promulgated pursuant to broad statutory authority and (3) "[b]ecause Congress has not 'directly spoken to the precise question at issue,'" *id.* at 457 (*citing Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-3 (1984)) this Court gave deference. *Id.* at 461. Yet none of these three prerequisites to *Auer* deference apply here. Unlike in *Auer* and *Riegel*, no regulation promulgated by the FDA is at issue. Likewise, Congress has not granted the FDA authority to address preemption via regulation. To the contrary, Congress recognized the role and primacy of common law, and expressly incorporated a savings clause. *Supra* at 4. Here no regulation is at issue, Congress' stance opposing preemption is unambiguous, and *Auer* deference therefore has no place. *Cf. Christensen v. Harris County*, 529 U.S. 576, 588 (2000) ("*Auer* deference is warranted only when the language of the regulation is ambiguous.").[9]

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[9] The United States' further citation to *Chevron U.S.A., Inc. v. National Resources Defense Counsel, Inc.*, 467 U.S. 837, 842-43 (1984) adds nothing to *Auer*, as the same limits apply. As this Court has noted, "Deference in accordance with Chevron...is warranted only 'when it appears that Congress delegated authority to the agency to make rules carrying the force of law, and that the agency interpretation claiming deference was promulgated in the exercise of that authority.'" *Gonzalez v. Oregon*, 46 U.S. 243, 257 (2006) (quoting *Mead Corp.*, 533 U.S. at 226-27 (*emphasis added*)).

While the United States cites *Geier v. American Honda Motor Corp.*, 529 U.S. 861 (2000) the deference afforded in that case was built on a far different foundation. As this Court discussed at length regarding the NHTSA's airbag and passive seatbelt research and regulation, "the relevant history and background are complex and extensive." *id.* at 883, noting that "DOJ has explained FMUSS 208's objectives, and the interference that 'no airbag' suits pose thereto consistently over time." *Id.* For this reason, the *Geier* majority concluded that "we have no reason to suspect that the Solicitor General's representation of DOT's views reflects anything other than the agency's fair and considered judgment on the matter." *Id.* at 884 (quoting *Auer*, 519 U.S. at 461-462).

In this case there is clearly neither the heavy involvement of Congress in the agency's decision, the extensive rulemaking, nor a consistent Agency position, as found in *Geier*. Rather, the record shows an agency willing to use a last-minute phone call on the eve of a holiday, and refusing to allow anyone to see its handiwork, to attempt a policy sea change by stealth.

The current argument of the Executive Branch presents, in starkest terms, the issue addressed by the dissent in *Watters v. Wachovia Bank, N.A.*, 127 S. Ct. 1559, 1582 (2007): whether *absent a delegation by Congress* to the agency of authority to preempt state laws (delegation the *Watters* opinion found had occurred under the National Bank Act but the FDA does not even claim here) "an administrative agency can assume the power to displace the

duly enacted laws of a state legislature." *Id.* at 1583 (Stevens, J., Roberts, C.J., and Scalia, J., dissenting). If the respect for state authority required by Federalism is to have any meaning *absent clear Congressional authorization* to preempt state laws, the answer must be:

> '[u]nlike Congress, administrative agencies are clearly not designed to represent the interests of States, yet with relative ease they can promulgate comprehensive and detailed regulations that have broad preemption ramifications for state law.' *Id.*, at 908, 120 S. Ct.. 1913 (STEVENS, J., dissenting). For that reason, when an agency purports to decide the scope of federal preemption, a healthy respect for state sovereignty calls for something less than *Chevron* deference. *See* 529 U.S., at 911-912; *see also Medtronic*, 518 U.S., at 512 (O'Connor, J., concurring in part and dissenting in part) ('It is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference').

Id. at 1584. Addressing the issue presented by the preamble before this court (and assuming, as shown here, no grant by Congress to the agency of authority to preempt) it was appropriately noted in the *Watters* dissent that, absent Congressional authority:

> Nor can the [Agency's] incorporation of that language into a regulation support

> the agency's position: 'Simply put, the existence of a parroting regulation does not change the fact that the question here is not the meaning of the regulation but the meaning of the statute.' *Gonzales v. Oregon*, 546 U.S. 243, 257 (2006). The OCC's argument to the contrary is particularly surprising given that when it promulgated its "same terms and conditions" regulation, it said not one word about preemption or the federalism implications of its rule—an inexplicable elision if a 'fundamental component' of the phrase is the need to operate unfettered by state oversight. Compare 65 Fed. Reg. 12905-12910 (2000), with Exec. Order No. 13132, §§ 2, 4, 64 Fed. Reg. 43255, 43257 (1999) (requiring agencies to explicitly consider the 'federalism implications' of their chosen policies and to hesitate before preempting state laws.

Id. at 1584-5.

Here, Congress has not provided the FDA any express or implied authority to determine the preemptive scope of its regulations on state law causes of action. The United States does not even try to claim any such clear and unambiguous delegation. This should be the end of the matter. As this Court noted in creating a "plain statement rule," preemption must come from *Congress* and "Congress should make its intention 'clear and manifest' if it intends to

preempt the historic powers of the states." *Gregory v. Ashcroft*, 501 U.S. at 461.

This Court's holding in *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 650 (1990), declining to give deference to the Secretary of Labor's view on the scope of civil remedies available to redress violations of regulations, also calls for non-deference. In *Adams Fruit*, this Court warned that, although agency determinations within the scope of delegated authority are entitled to deference, it is fundamental "that an agency may not bootstrap itself into an area in which it has no jurisdiction." *Id.* Likewise, an agency ruling that broadens its own jurisdiction should be carefully scrutinized. *See, e.g., Hi-Craft Clothing v. NLRB*, 660 F.2d 910, 916 (3d Cir. 1981). Courts should be skeptical of the FDA's assertion of power, as it is highly unlikely that Congress would implicitly delegate to the agency the power to define the scope of its own power. *See Ass'n of American Physicians & Surgeons v. United States Food & Drug Admin.*, 226 F. Supp. 2d 204, 212 (D.D.C. 2002) (finding that the FDA exceeded its authority in adopting regulations requiring drug manufacturers to conduct certain testing on pediatric populations).

Here, Congress has never delegated to the FDA authority to determine the preemptive effect of drug labeling rules on state law causes of action. To the contrary, as noted above at 4, Congress specifically declined to provide a federal damages remedy in the FDCA because state law damages remedies were available and subsequently added a savings clause. Having made no effort to legislate on the topic of

drug-related damages remedies, and then adding a savings clause to preserve the remedies provided by State law, Congress can hardly be said to have authorized the FDA to supersede the damages remedies traditionally provided by the states, let alone to have made a "plain statement" of intent to preempt. *See Gregory v. Ashcroft*, 501 U.S. at 460-61.

The preamble does not merely preempt or preclude the development or enactment of some yet-inchoate State law. What we know as "the common law" is both vast and specific, woven over decades into a rich tapestry, interpreting and elaborating on State statute, and in turn being hemmed and bordered by it. As Justice Holmes observed famously, "the common law is not a brooding omnipresence in the sky but the articulate voice of some sovereign or quasi-sovereign that can be identified . . . it is always the law of some State . . ." *Southern Pacific v. Jensen*, 24 U.S. 205, 222 (1917) (dissent); cited, *inter alia*, in *American Dredging Co. v. Miller*, 510 U.S. 443, 459 (1994) and *Salve Regina College v. Russell*, 499 U.S. 225, 238 (1991).

These principles, combined with Congress' express rejection of a proposal to include a federal private right of action in the FDCA because "a common law right of action already exists," and the absence of any provision within the FDCA delegating to the FDA authority to determine the preemptive effect of drug labeling rules on state law causes of action, leads to one conclusion—Congress could not have, and did not, confer upon the FDA the power to legislate for itself and unilaterally determine whether its

drug labeling regulations preempt state law. Therefore, the FDA's proposed preemption analysis is nothing more than an *ultra vires* political statement which exceeds the scope of the FDA's congressional authority and, as such, is due no deference from this Court.

C. The Preamble's Reversal of the FDA's Longstanding Position Against Preemption Undermines the Argument for Deference.

Assuming that the FDA had the requisite congressional authority to determine the preemptive scope of its regulations—which it plainly did not—deference is nevertheless unwarranted because the preamble reverses the FDA's longstanding position against preemption. As has been noted by several courts: "FDA's current view of the preemptive effect of its labeling regulations is a 180-degree reversal of its prior position." *In re Bextra and Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. M:05-169 CRB, 2006 WL 2374742 at 18 (N.D. Cal. Aug. 16, 2006). This has caused courts, in reasoned opinions, to reject the preamble and the FDA's claims of preemption. *See, e.g.*, *In re Vioxx Prod. Liab. Lit.*, 501 F.Supp 2d 776 (E.D. La. 2007) (noting change in prior position and refusing to give the preamble *Auer* or *Chevron* deference).

This Court has repeatedly held that an agency assertion of preemption that reverses prior longstanding agency policy is entitled to little or no weight by the courts. *See Bates v. Dow Agrosciences, L.L.C.*, 544 U.S. 431, 449 (2005). In *Bates*, this Court

ruled that FIFRA, a federal statute governing the safety of pesticides, did not preempt state common law tort claims. In doing so, this Court rejected arguments made by the government in *amicus* briefs, and in fact chastised the EPA for engaging in the exact same policy flip-flop at issue herein: "The notion that FIFRA contains a nonambiguous command to pre-empt the types of tort claims that parallel FIFRA's misbranding requirements is particularly dubious given that just five years ago the United States advocated the [opposite interpretation]." *Id.*

As in *Bates*, this Court should greet skeptically any suggestion that the FDA's drug labeling requirements preempt state law, given that the FDA itself advocated the opposite interpretation just six years ago. The similarities between the nature and timing of the EPA's conduct in *Bates* and the FDA's conduct herein demand careful consideration of the strict adherence to the "canons of interpretation" favoring principles of *stare decisis* over the more volatile political opinions within federal agencies. *Bates*, 544 U.S. at 449.

As set forth above, the FDA's abrupt change in position regarding the preemptive scope of its drug labeling requirements reverses an anti-preemption policy which spanned decades, including an express statement by the FDA in 2000 that: "this proposal does not preempt state law." 65 Fed. Reg. 81082, 81103 (2000). During this time, numerous courts throughout the country relied on the FDA's interpretation of its regulations while continuing the grand and endless project of developing and refining a sub-

stantial body of state common law,[10] and for rejecting the very same preemption arguments made herein. Importantly, the final rule does not amend any of the regulations upon which these courts have relied in finding no preemption. Accordingly, the FDA's abrupt change in position unnecessarily disrupts not only its own longstanding principles, but principles of *stare decisis* as well.

Ultimately, the FDA's preamble is simply an unwarranted and arbitrary change in position without any concomitant change in the law. For these reasons, the Court should give no deference.

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[10] As California Chief Justice Roger Traynor observed of the common law process, "The law was not built in a day, and with luck it will never be finished." Traynor, "*La Rude Vita, La Dolce Giustizia; or Hard Cases Can Make Good Law*," 29 U. Chi. L. Rev. 223, 236 (1962). It would be unlucky indeed for our system of Federalism were an administrative agency to finish off the common law of tort with a "preamble."

CONCLUSION

For the preceding reasons, the judgment of the Supreme Court of Vermont should be affirmed.

Respectfully submitted,

ELIZABETH J. CABRASER
COUNSEL OF RECORD
SCOTT P. NEALEY
LIEFF, CABRASER, HEIMANN & BERNSTEIN, LLP
275 BATTERY STREET, 30TH FLOOR
SAN FRANCISCO, CA 94111-3339
TELEPHONE: (415) 956-1000
FACSIMILE: (415) 956-1008

COUNSEL FOR AMICUS CURIAE

No. 06-1249

In the Supreme Court of the United States

WYETH,

Petitioner,

v.

DIANA LEVINE

Respondent.

On Writ of Certiorari to the Supreme Court of Vermont

AFFIDAVIT OF SUSAN PARNAS FREDERICK

AFFIDAVIT

I, Susan Parnas Frederick, do hereby testify as follows under penalty of perjury.

I am the Federal Affairs Counsel for the National Conference of State Legislatures. I am a member of the bar of the Commonwealth of Virginia. In my responsibility as Federal Affairs Counsel for the National Conference of State Legislatures, I am responsible for acting as the liaison to the Executive Branch for State legislatures regarding Executive Order 13132 ("Federalism").

On December 2, 2000, the Food and Drug Administration submitted a Notice of Proposed Rule Making ("NPRM") regarding prescription drug labeling. *See Federal Register*, Volume 65, Number 241, p. 81103, December 22, 2000. Because the NPRM expressly stated that there would be no Federalism implications in the regulation, and because the proposed rule stated that it would not preempt state laws, the National Conference of State Legislatures did not submit comments. Because the Regulation expressly stated that there would be no preemption, the formal consultation requirements of Executive Order 13132 were not triggered.

At the end of the day on December 30, 2005, I received a call in my office from FDA intergovernmental staff. This staffer told me that the FDA planned to finalize its long-dormant labeling rule in early January 2006 and would be including a statement that the provisions of the Prescription Drug Labeling Rule would preempt state product liability laws. I immediately asked to be placed in touch with FDA's general counsel's office, asked for a copy of the pro-

posed "policy statement," for the consultation process under Executive Order 13132 to occur, and for the Notice and comment period to be re-opened. Upon receiving a call from general counsel's office for the FDA, I was informed by Mr. Randy Luttig that NCSL could not review this proposed language in advance of its publication, that this telephone call constituted the consultation under Executive Order 13132, and that the comment period was closed and would not be reopened to permit NCSL to submit comments on the new language.

In a follow-up conversation with FDA staff, I was informed that the FDA considers the requirement of Executive Order 13132 satisfied, and was again told I would not be able to review a copy of the proposed "policy statement," I subsequently learned that FDA had received and accepted numerous late, non-public, comments from industry on the proposed regulation.

Because the FDA had refused to follow the process required by Executive Order 13132, which requires that meaningful consultation with state officials or their national associations is to occur *prior* to any notice of proposed rule making being published in the Federal Register our organization wrote to Secretary Leavitt to complain about the FDA's conduct. *See* http://www.ncls.org/programs/press/2006/060113leavitt.htm.

The foregoing is true and correct, and if called to I could testify competently thereto.

Dated: August 14, 2008.

Susan Parnas Frederick

Susan Parnas Frederick